IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	Art Unit: 1645
PEDERSEN, et al.	)	Examiner: TONGUE, L.
Serial No.: 10/541,068	)	Washington, D.C.
Filed: May 15, 2006	)	September 18, 2008
For: ANTIMICROBIAL COMPOSITION FOR LOCAL USE ON MUCOSAL MEMBRANES AND SKIN	)	Docket No.: PEDERSEN=13 Confirmation No.: 6078

ELECTION WITH TRAVERSE

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S i r :

In response to the restriction requirement mailed June 26, 2008, please enter the following remarks.

1. Applicants elect group I with traverse.

2. PCT unity rules apply. The restriction is based on a holding of a posteriori lack of unity based on the alleged anticipation or obviousness of claim 1 by or over Stephan, USP 4,734,279. We believe that this holding is improper.

The problem that is solved by the present invention is to make Gram negative bacteria accessible to lysozyme. This is done by exposing them to a mixture of lysozyme and immunoglobulins that have been glycosylated synthetically.

Normally, the peptidoglycan layer of Gram negative bacteria is inaccessible for lysozyme due to the presence of a lipopolysaccharide layer of the bacteria. The presence of glycosylated immunoglobulins seems to confer new properties to the immunoglobulin upon attachment to the bacterial cell wall leading to altered conformation of the bacterial cell wall. This results in the accessibility of lysozyme to the underlying paptidoglycan layer and subsequent degradation of Gram negative bacteria (Examples 1 and 2).

Even though compositions as described by Stephan et al.

would contain native glycosylated immunoglobulins, the present invention discloses immunoglobulins that have been additionally glycosylated by incubating native immunoglobulins "in a solution comprising disaccharide or monosaccharide" (claim 1), e.g., in a solution of glucose as described on page 9.

Glycosylation confers protection of immunoglobulins against for example bacterial proteases. Additional glycosylations will thus result in a larger fraction of immunoglobulins that will be resistant to bacterial proteases and the immunoglobulins will remain functional for a more prolonged period of time after administration as compared to native immunoglobulins.

Stephan et al. discloses a pharmaceutical composition comprising immunoglobulins and lysozyme. In col. 4 lines 6 -12 is described how the lysozyme cleaves between N-acetylmuraminic acid and N-actylglucosamine constituting the peptidoglycan layer of the bacterial cell wall, whereby lysis of the bacterium occurs. The resulting cell fragments are captured by immunoglobulins whereby the fragments may be supplied to immune cells and thus eliminated.

Stephan et al. does not disclose synthetically glycosylated immunoglobulins. Thus, the present invention is novel in view of U.S. Patent 4,734,279.

Furthermore, Stephan et al. has not solved the problem of Gram negative bacteria being inaccessible to lysozyme due to the lipopolysaccharide layer in the bacterial cell wall. The composition of Stephan et al. will not be able to lyse Gram negative bacteria. Furthermore, the half-life of the immunoglobulins of Stephan et al. has not been prolonged. Thus, the present invention is non-obvious over U.S. Patent 4,734,279.

In conclusion, the present invention is novel over prior art due to the synthetic glycosylation of immunoglobulins, thereby conferring new and improved features to the combined effect of lysozyme and immunoglobulins already known in the art. The present invention solves a problem, not already solved by Stephan et al. in regard to both prolonged half-life of the glycosylated

immunoglobulins and effectiveness against Gram negative bacteria.

Consequently, the restriction should be withdrawn.

3. Moreover, since claim 1 is allowable, rejoinder of groups II (method of making composition of claim 1) and III (method of using composition of claim 1) is proper under MPEP 821.04.

Respectfully submitted,

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